

Applicants appreciate that the Examiner has brought to their attention that the Declaration filed August 16, 2004 is defective in that an alteration made to Dr. Xiang-Jin Meng's country of citizenship had been initialed by Dr. Meng but not dated. To promptly cure this inadvertent oversight and provide Dr. Meng's recently acquired citizenship in the United States of America in the Official record, a supplemental Declaration for Utility Patent Application in compliance with 37 C.F.R. § 1.67(a) is submitted herewith. Applicants respectfully ask the Examiner to please confirm that the supplemental Declaration meets the statutory standard.

Applicants also gratefully acknowledge that the Examiner generously withdrew several of the prior rejections described on pages 2-4 of the current Office action and she kindly finds that Claims 1-3 and 32 are allowed.

In this Office action, the Examiner now applies a new rejection of Claims 4-10, 15, 16 and 18-22 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for reasons given on pages 4 and 5 of the Office action. Without comment as to the merits of the rejection but to advance prosecution towards an allowance, the pending claims have been amended for the better readability thereof. It is further noted that although the Examiner had made no comment regarding Claim 15(a), appropriate revision of Claim 15(a) has been made to conform its language to the Examiner's suggested language for Claim 4. In view of the amendment, Applicants respectfully ask that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

Also newly applied, Claims 4-10, 15, 16 and 18-22 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement for reasons given on pages 5 and 6 of the Office action. Basically, the Examiner believes that Applicants have not adequately demonstrated possession of the embodiment of the claims drawn to a chimeric nucleic acid molecule (PCV1-2 construct) having at least 95% homology to the nucleotide sequence of SEQ ID NO:2. Applicants respectfully traverse the rejection for the following reasons.

It is well established that the question whether a disclosure satisfies the written description requirement is not answered by examining the specification for the presence or absence of literal support for the claim language (see, *e.g.*, *Ex parte Harvey*, 3 U.S.P.Q.2d 1626 (B.P.A.I. 1986); *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976)). Rather, the key to compliance

with the requirement is a determination that the disclosure reasonably conveys to the person of ordinary skill in the art that the inventor had possession of the specific subject matter, as of the filing date.

In the case at hand, the specification describes that the invention includes the nucleotide sequences having at least 95% homology to the chimeric nucleotide sequence (see page 18, lines 1-18 of the application). The 95% high homology recited in the present claims is a modest limit of nucleotide identity that is consistent with the broader teachings in the art, namely, that the nucleotide sequences of PCV2 isolates can actually vary from 80% to 99% of nucleotide sequence homology.

As taught in the application on page 21, line 6, the sequences of all known PCV2 field isolates identified to filing date are very conserved. The person of ordinary skill in the art would be familiar with the significant amount of literature describing the conserved portions of the PCV2 nucleic acid molecule and the percentage variation of nucleotide sequence homology (a sampling of the numerous articles cited in the background of the invention includes, for example, M. Fenaux *et al.*, "Genetic characterization of type 2 porcine circovirus (PCV-2) from pigs with postweaning multisystemic wasting syndrome in different geographic regions of North America and development of a differential PCR-restriction fragment length polymorphism assay to detect and differentiate between infections with PCV-1 and PCV-2," J. Clin. Microbiol. 38:2494-503 (2000); A. L. Hamel *et al.*, "Nucleotide sequence of porcine circovirus associated with postweaning multisystemic wasting syndrome in pigs," J. Virol. 72:5262-5267 (1998); *etc.*).

Further precedent in support of the claimed subject matter is seen in U.S. Patent No. 6,703,023 in which Claim 1 is drawn to a vaccine for protection against infection by a piglet weight loss disease circovirus that comprises a nucleic acid having a nucleotide sequence with **at least 90% sequence identity** to a particular sequence (see also col. 7, line 1 to col. 8, line 2 disclosing a percentage identity with the bases of a nucleotide sequence according to the '023 invention of at least 80%, 90% or 95%) and U.S. Patent No. 6,287,856 in which Claim 1 is drawn to an isolated nucleic acid comprising a nucleic acid having a nucleotide sequence with **90% or greater homology** to fifteen different sequences. It is clear that the artisan would have no doubt that the Applicants had possession of their nucleotide sequences having *at least 95% homology* to the nucleotide sequence of SEQ ID NO:2 described in the present application.

In view of the foregoing remarks and the proffered evidence, Applicants respectfully ask that the Examiner kindly withdraw the rejection of the pending claims under 35 U.S.C. § 112, first paragraph, rejoin the process claims and allow the application to issue as a patent.

If any outstanding issue remains in this case, the Examiner is invited to contact the undersigned attorney to discuss mutually agreeable solutions.

Accordingly, it is believed that this application is now in condition for an allowance. Favorable treatment is respectfully urged.

Respectfully submitted,

VIRGINIA TECH INTELLECTUAL  
PROPERTIES, INC. and IOWA STATE  
UNIVERSITY RESEARCH  
FOUNDATION, INC.

Date: May 16, 2006

By: Anne M. Rosenblum  
Anne M. Rosenblum  
Attorney for Applicants  
Registration No. 30,419

FILING BY EXPRESS MAIL UNDER 37 C.F.R. § 1.10

This correspondence is being deposited with the U.S. Postal Service on May 16, 2006 to be delivered by the "Express Mail Post Office to Addressee" service under Mailing Label Number EQ 269458414 US addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Anne M. Rosenblum  
Anne M. Rosenblum